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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,063	10/24/2000	Linda Gillian Durrant	0380-P02286U	5686

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EXAMINER
SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
1644	11

DATE MAILED: 06/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/623,063	Durrant et al.
Examiner	**Art Unit**
R n Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 22, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *42-101* is/are pending in the application.

4a) Of the above, claim(s) *42-63, 68-70, 72-74, 77-94, and 96-101* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *64-67, 71, 75, 76, and 95* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Applicants' election with traverse of Group IX, claims 64-67,71,75,76,95 and the species peptide z32 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that are stated in said paper. This is not found persuasive because of the following reasons. The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The claims lack the same or corresponding special technical features because they are anticipated or obvious over the prior art. Breitman et al. (US Patent 5,681,714) teach polyclonal antibodies made against Tek (see column 18 and 4 wherein the disclosed protein is Tek). Said antibodies would bind the peptides recited in the claims because polyclonal antibodies against TEK would bind all immunogenic epitopes expressed by said molecule. Regarding applicants comment about "specific antibody", the claims do not recite that the antibody is monospecific. In fact, the claims do not even recite that the antibody is purified. The claimed antibody reads on a polyclonal antibody preparation which contains the antibody of claim 56. In addition, the elected claims lack a special technical feature in that they are rejected over the prior art for the reasons elaborated in the instant Office Action.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 42-63,68-70,72-74,77-94,96-101 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed in paper No. 10.

3. Claims 64-67,71,75,76,95 are under consideration.

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

5. The first line of the specification should be amended to recite "This application is a 35 U.S.C. 371 of PCT GB99/00583, filed February 26, 1999.".

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 64-67,71,75,76,95 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "substantially free of sequences which are not part of said at least one MHC-binding epitope of Tek" in claim 64 (which recites that the peptide is the peptide of claim 42). Applicant has not indicated where said limitation finds support in the specification as originally filed. Original claim 5 discloses an epitope *polymer* wherein the sequence is "substantially devoid of the amino acid sequence that occurs between the neighbouring epitopes". However, said disclosure is not a disclosure of a monomer epitope with said limitation. Furthermore, the specification lacks a definition of "substantially devoid" in the context recited in the claims. Said term also lacks an art recognized meaning in the context recited in the claims. Therefore, it is unclear whether said term and "substantially free" has the same meaning/scope in the context recited in the claims There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

8. Claims 64-67,71,75,76,95 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed inventions.

The instant claims encompass immunogenic MHC binding Tek peptides derived from any mammalian Tek. There are more than four thousand species of mammals whilst the specification discloses only MHC binding Tek peptides derived from human Tek. In addition, the art recognizes that there are hundreds of MHC class I and class II alleles in humans wherein said molecules bind different and largely nonoverlapping sets of peptides derived from the same protein. The specification only provides the identity of three or four peptides which bind a single class I allele (HLA-A2), and stimulate T cell proliferation (eg. are immunogenic). The specification also appears to disclose four peptides which bind several different class II (HLA-DR) alleles. However, the art recognizes that there are hundreds of MHC class I and class II alleles in humans wherein said molecules bind different and largely nonoverlapping sets of peptides derived from the same protein. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification has disclosed a few specific immunogenic peptides derived from human Tek, while claiming immunogenic MHC binding peptides derived from any mammal and peptides which bind any human MHC class I or II allele. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373

(Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 64-67,71,75,76,95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 64,67 and 71 are indefinite in that they depend from nonelected claim 42. Claims 64,65 are indefinite in that a product claim should recite a single product wherein claims 64 and 65 recite two different products (eg. a recombinant DNA construct or a virus vector). Claim 64 is indefinite in the recitation of "substantially free of sequences which are not part of said at least one MHC-binding epitope of Tek". It is unclear what said limitation means or encompasses. Said term is not defined in the specification and has no art recognized meaning in the context recited in the claim. For example, it is unclear as to what number of actual amino acid residues outside the MHC-binding epitope would be encompassed by "substantially free of sequences". It is unclear if the aforementioned limitation would encompass an epitope plus 5 amino acids or 50 amino acids, etc.

11. Regarding the term Tek as recited in the claims, the specification discloses that Tek (a.k.a. tie-2) is the protein disclosed in various prior art references recited in page 1 of the specification.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

13. Claims 64-67,71,75,76,95 are rejected under 35 U.S.C. 102(b) as being anticipated by Breitman et al. (US Patent 5,681,714) as evidenced by Rammensee et al.

Breitman et al. teach nucleic acids encoding fragments of Tek (see column 14, last two paragraphs). Breitman et al. teach that said nucleic acids can be incorporated in to suitable vectors/plasmids and host cells containing the necessary regulatory elements required for transcription/translation (see column 14 and 15). Breitman et al. teach Tek fragments that can be used to produce antibodies and recombinant production of said fragments (see column 18, first paragraph). Breitman et al. teach a DNA fragment encoding 43 amino acids of Tek which was subcloned into an appropriate expression vector/host cell (see column 34, third complete paragraph). In view of the fact that the claims encompass MHC binding peptides wherein the MHC molecule could be derived from any of at least 4000 known mammals and the fact that each species would have potentially hundreds of different alleles which bind different peptides, it would be reasonable to assume that at least one such MHC molecule from one species would bind the peptide fragment encoded by the nucleic acid taught by Breitman et al. Furthermore, Rammensee et al. teach that MHC binding peptides usually contain certain defined anchor residues wherein the peptide taught by Breitman et al. contains such anchor residues (eg. see Rammensee, page 200, HLA-B*2705, etc). Thus, it is an inherent property of said peptide that it contains an MHC binding peptide. While it is not clear what "substantially free of sequences which are not part of said at least one MHC-binding epitope of Tek" means or encompasses, for the purposes of this rejection the term will be interpreted as meaning not containing a large majority of the nonMHC binding amino acids found in intact Tek (as per the 43 amino acid fragment taught by Breitman et al.). The peptide encoded by the nucleic acid taught by Breitman et al. stimulates an immune response (eg. Induces antibody formation).

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1900~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644